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6/4/02 *Margaret K. Klopping*
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:
Richard H. PETERS et al.

Serial No.: 09/780,990

Group Art Unit: 1616

Filing Date: February 9, 2001

Examiner: S. QAZI

Title: SYNTHESIS OF ANTI-ESTROGENIC AND OTHER THERAPEUTIC STEROIDS
FROM 21-HYDROXY-19-NORPREGNA-4-EN-3-ONE

RESPONSE TO REQUIREMENT FOR RESTRICTION AND ELECTION OF SPECIES

Commissioner for Patents
Washington, DC 20231

Sir:

This is in response to the Office Action mailed March 4, 2002. A request for a two-month extension of time to respond accompanies this response. In the Office Action, the Examiner required restriction between the following seventeen groups of claims:

- I. Claims 1-5, drawn to compounds of formula (I);
- II. Claims 6-13, drawn to compounds of formula (III);
- III. Claims 14-18, drawn to compounds of formula (V);
- IV. Claim 19, drawn to compounds of formula (XVII);
- V. Claims 20, 36 and 40, drawn to compounds of formula (XVIII), a composition containing such a compound, and a method of use;
- VI. Claims 21, 37 and 41, drawn to compounds of formula (VII), a composition containing such a compound, and a method of use;
- VII. Claims 22-25, drawn to compounds of formula (XVI);
- VIII. Claim 26, drawn to a method for synthesizing the 21-hydroxy-19-nor pregnane of formula (I);

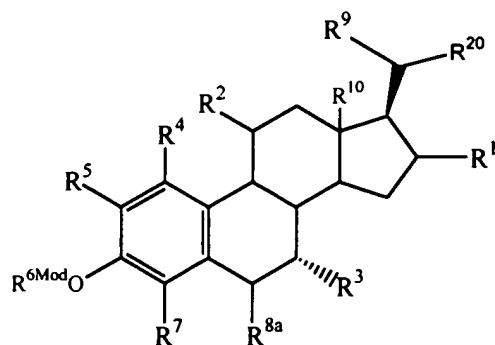
- IX. Claim 27, drawn to a method of preparing the 21-hydroxy-19-nor pregnane of formula (IX);
- X. Claim 28, drawn to a method of synthesizing a 7-alkyl-6-keto-1,3,5(10) estratriene;
- XI. Claim 29, drawn to a method of synthesizing a 7-alkyl-6-keto-1,3,5(10) estratriene of formula (VIa);
- XII. Claims 30 and 31, drawn to a method for preparing compounds of formula (XI);
- XIII. Claims 32 and 33, drawn to a method for preparing compounds of formula (XI);
- XIV. Claims 34 and 35, drawn to a method for preparing compounds of formula (XI);
- XV. Claims 38 and 42, drawn to a pharmaceutical composition containing 17-[2-(4-diethylaminomethyl-2-methoxy-phenoxy)-ethyl]-13-methyl-cyclopenta[α]phenanthren-3-one and a method for treating a prostate disorder with the compound;
- XVI. Claims 39 and 43, drawn to a pharmaceutical composition containing 17-[2-(4-diethylaminomethyl-2-methoxy-phenoxy)-ethyl]-7 α ,13-dimethyl-cyclopenta[α]phenanthren-3-one and a method for treating a prostate disorder with the compound; and
- XVII. Claim 44, drawn to the method of preparing 17-[2-(4-diethylaminomethyl-2-methoxy-phenoxy)-ethyl]-7 α ,13-dimethyl-cyclopenta[α]phenanthren-3-one.

The Examiner has also required that the applicants elect a single disclosed species for initial examination.

RESPONSE TO RESTRICTION REQUIREMENT:

In response, applicants elect Group III, claims 14-18, and traverse the restriction insofar as the claims of Group VI, claims 21, 37, and 41, should be included with the claims of Group III. The claims of Group III are drawn to a compound having the structural formula (V)

(V)



wherein:

R^1 is hydrogen or $CR^{11}R^{12}$, wherein R^{11} and R^{12} are hydrogen or lower alkyl;

R^2 is selected from the group consisting of hydrogen, hydroxyl, alkyl, $-OR^{13}$, and $-SR^{13}$

wherein R^{13} is alkyl;

R^3 is selected from the group consisting of hydrogen and hydrocarbyl, preferably hydrogen and alkyl, e.g., lower alkyl such as methyl;

R^4 , R^5 , and R^7 are independently selected from the group consisting of hydrogen and lower alkyl;

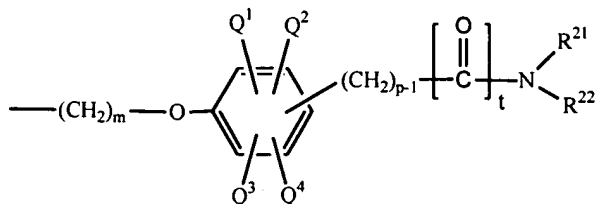
R^{6Mod} is selected from the group consisting of hydrogen, alkyl, acyl, $-C(O)$ -aryl, and $-C(O)$ -alkyl, hydroxyl-protecting groups, and hydroxyl-activating groups;

R^{8a} is selected from the group consisting of hydrogen, hydroxyl, oxo, and $-OR^{18}$ wherein R^{18} is lower alkyl or lower acyl;

R^9 is hydrogen or alkyl;

R^{10} is methyl or ethyl; and

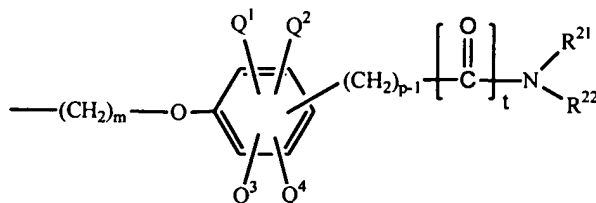
R^{20} is hydroxyl, hydroxymethyl, protected hydroxyl, protected hydroxymethyl, activated hydroxyl, activated hydroxymethyl, or



in which m is zero or 1, p is an integer in the range of 1 to 7 inclusive, and t is zero or 1, with the proviso that when R^{8a} is oxo, t is 1, and R²¹ and R²² are lower alkyl or are linked together to form a five- or six-membered heterocycloalkyl ring; and

Q¹, Q², Q³, and Q⁴ are independently selected from the group consisting of hydrogen, hydroxyl, carboxyl, alkoxy, alkyl, halogen, amino, and alkyl-substituted amino.

The claims of Group VI are drawn to compounds and compositions containing compounds having the structure of formula (VII), which is a subset of the compositions having the structure of formula (V) wherein R², R⁴, R⁵, R⁷, and R⁹ are hydrogen, R^{8a} is the subset R^{8b} (hydrogen, hydroxy, or oxo), R¹⁰ is methyl, and R²⁰ is



As all of the compounds recited in the Group VI claims fall within the scope of the Group III claims, the two claim groups are properly examined together. Applicants expressly reserve their right under 35 USC §121 to file divisional applications directed to the nonelected subject matter during the pendency of this application.

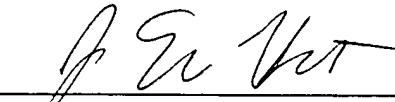
RESPONSE TO ELECTION OF SPECIES REQUIREMENT:

With regard to the Examiner's request for election of species, applicants elect the species N,N-Diethyl-4-[2-(3-hydroxy-7,13-dimethyl-7,8,9,11,12,13,14,15,16,17-decahydro-6H-cyclopenta[α]phenanthren-17-yl)-ethoxy]-3-methoxy-benzamide, indicated as compound 18 in FIG. 5 in the specification. Within the Group III and Group VI claims, claims 14, 21, 37, and 41 read on the designated species. It is to be understood that this election of species is for the sole purpose of the Examiner's initial search and examination, and that all non-designated species will be examined upon allowance of a generic claim.

If the Examiner has any questions concerning this communication, or would like to discuss the application, the art, or other pertinent matters, she is welcome to contact the undersigned attorney at 650-330-0900.

Respectfully submitted,

By: _____


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